

Lynch Screening Database Elements - Draft 4

Automatic unique number generated for each subject that designates which site/registrant is entering vs. center using own pt id number with "site/registrant" prefix.

I. Demographics/History:

- a. **Age at Diagnosis** - open 2 digit with check box option for 85+ (vs. drop down with ages/ranges)
- b. **Sex – drop down**
- c. **Race** - drop down (Cauc, Black, Asian, etc.)
- d. **Insurance** - drop down (public, private, none, unknown)
- e. **Previous Lynch Syndrome-related Cancer (yes/no)** - may need option for more than one previous cancer
 - i. **Type** (colon, endometrial, ovarian, other (specify))
 - ii. **Age of diagnosis**
- f. *Previous* diagnosis of Lynch syndrome
 - i. **In patient** (Yes/No)
 1. If Yes - mutation identified (Yes/No)
 - a) Yes - drop down (MLH1,MSH2, MSH6, PMS2, EPCAM, constitutive MLH1 epimut)
 - ii. **In family member** (Yes/No)
 2. If yes - specify relationship (drop down with options?)
 3. If Yes - mutation identified (Yes/No)
 - a) Yes - drop down (MLH1,MSH2, MSH6, PMS2, EPCAM, constitutive MLH1 epimut)

II. Index Cancer (date of diagnosis)

- a. **Type** - drop down (Colon, Endometrial, Ovarian, other - specify)
 - i. If colon selected:
 1. **Site** (rectal, distal, transverse, proximal)
 - a) **Synchronous tumors** - Yes/No
 - b) If YES - **Site** of 2nd tumor (rectal, distal, transverse, proximal)
- b. **Stage** - drop down (item tentative, choices to be determined)

III. Tumor Screening

- a. **MSI Testing** - Yes/No
 - i. If Yes - **Results** (drop down - high, low, stable)(date)
- b. **IHC Testing** - Yes/No
 - i. If Yes - **Results**: (date) (This might work best in table)
 1. MLH1 (present, absent, indeterminate, not done)
 2. MSH2 (present, absent, indeterminate, not done)
 3. MSH6 (present, absent, indeterminate, not done)
 4. PMS2 (present, absent, indeterminate, not done)
- c. **BRAF V600E Testing** - Yes/No
 - i. If Yes - **Results** (positive, negative)(date)
- d. **MLH1 Promoter Methylation Analysis** - Yes/No
 - i. If Yes - **Results** (positive, negative)(date)

IV. Tumor Screening Positive (abnormal results) - Yes (proceed)/No (Stop)

- a. Follow-up completed - Yes/No
 - i. If No - **Reason** (pending, lost to follow-up, patient refused, other-specify)
 - ii. If Yes:
 1. **Referred for Genetic Counseling** - Yes/No
If No - **Reason** (drop down - Counseling not available, not part of protocol, other....)
 2. **Genetic Counseling Completed** - Yes/No (If yes - date)

If No - **Reason** (drop down - patient did not desire counseling, insurance would not cover, did not return for counseling appointment, other - specify)

3. Family History: Negative/Positive/Unknown

a) If Positive:

a. **Amsterdam Criteria Met** - Yes/No

b. **Bethesda Criteria Met** - Yes/No

If both of above No:

1st degree relative with colon cancer - Yes/No

1st degree relative with endometrial cancer - Yes/No

1st degree relative with other Lynch cancer - Yes/No

2nd degree relative with colon cancer - Yes/No

2nd degree relative with endometrial cancer - Yes/No

2nd degree relative with other Lynch cancer - Yes/No

4. Genetic Testing (DNA Analysis) Performed - Yes/No

a) If Yes - **Results:** (date - for each)(This also would work well in a table)

a. MLH1 sequencing (positive, negative, VUS, not done)

b. MLH1 large rearrangement testing (positive, negative, not done)

c. MSH2 sequencing (positive, negative, VUS, not done)

d. MSH2 large rearrangement testing (positive, negative, not done)

e. EPCAM rearrangements (positive, negative, not done)

f. MSH6 (positive, negative, VUS, not done)

g. MSH6 large rearrangement testing (positive, negative, not done)PMS2 sequencing (positive, negative, VUS, not done)

h. PMS2 large rearrangement testing (positive, negative, not done)

i. Other testing performed: (blank or drop down to be determined)

1) If any of a-i “positive” for LS:

Family member tested - Y/N

If Yes - need option for several entries: (Table would work here w/ column for result pos/neg and date)

Relationship: (son, daughter, brother, sister, mother, father, niece, nephew, paternal grandparent, paternal aunt/uncle, paternal 1st cousin, maternal grandparent, maternal aunt/uncle, maternal 1st cousin

For each relative entered - result: positive/negative

2) If a-i are all “negative” for LS:

Surveillance recommendations (open or drop down tbd)

b) If No - **Reason** (patient did not desire testing, insurance would not cover, did not return for testing, other - specify)